REMARKS

The Amendments

Claims 12 and 15 are amended to replace the term "non-injectable form" with "in a form suitable for enteral but not parenteral administration." See, e.g., page 5, lines 9-29, of the specification. The amendment was made in view of the objection in the Office Action to the "non-injectable" term. Although applicants disagree with the objection, the new language is provided since it does not narrow the scope of the claims and may be considered more suitable to the Examiner. The specification clearly contemplates the options of using forms, which are optionally for enteral administration and optionally for parenteral administration. Thus, it adequately describes forms, which are suitable for enteral administration but not suitable for parenteral administration. See the attached Kendall Declaration. New claims 42 and 43 are supported by applicants' disclosure as whole, see, e.g., page 5, lines 28-29, disclosing the option of sterilizing. See also the discussion of the 35 U.S.C. §112 rejection below.

The amendments should not be interpreted as an acquiescence to any objection or rejection made in this application. To the extent that the amended claims are interpreted as avoiding the prior art or having been made for other reasons related to patentability, competitors are warned that the amendments are not intended to and do not limit the scope of equivalents which may be asserted on subject matter outside the literal scope of any patented claims but not anticipated or rendered obvious by the prior art or otherwise unpatentable to applicants. Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application, which has been canceled by any of the above amendments.

The Restriction Requirement

Because the non-elected method claims require the particulars of the composition or kit claims – i.e., they are dependent thereon – rejoinder of the method claims is requested upon a finding of allowability of the composition and/or kit claims. See, e.g., <u>In re Ochiai</u>, 37 USPQ2d 1127 (Fed. Cir. 1995); <u>In re Brouwer</u>, 37 USPQ2d 1663 (Fed. Cir. 1996); and the Commissioner's Notice regarding them at 1184 TMOG 86, March 26, 1996.

The Drawings

New drawings are submitted, as required in the Office Action, to address the informalities noted in the PTO-Form 948.

The Rejection under 35 U.S.C. §112, first paragraph

Although the amended claims do not contain the language which formed the basis for the rejection under 35 U.S.C. §112, first paragraph, applicants submit the following traversal of the rejection because they disagree with the rejection and the legal issue involved is likely pertinent to the amended claims as well.

The rejection was based on the allegation that the original disclosure did not support "non-injectable" forms of the components. Granted, the specification does not recite the word "non-injectable" per se. But it does recite the optional use of certain injectable forms, i.e., it discloses that these injectable forms "can" be used but are not required (page 5).

Applicants respectfully urge that, when a disclosure recites an element as being optional, it

It being well settled that the subject matter of a claim need not be described in the specification literally or "in ipsis verbis" in order for the specification to satisfy the description requirement of 35 U.S.C. §112, first paragraph. See <u>Kennecott Corp. v. Kyocera International, Inc.</u>, 5 USPQ2d 1194, 1197 (Fed. Cir. 1987); and <u>In re Wertheim</u>, 191 USPQ 90, at 98 (CCPA 1976).

adequately describes under 35 U.S.C. §112, first paragraph, both the option of inventions meeting the recitation of that element and the option of inventions not meeting the recitation of that element. See, e.g., Ex parte Cordova, 10 USPQ 2d 1949 (Bd. App. 1988), and Ex parte Wu, 10 USPQ 2d 2031 (Bd. App. 1988), regarding this clear interpretation of an optional term in claims.

In the instant case, therefore, it is urged that "non-injectable" forms of the components were supported by the disclosure describing optional use of injectable forms.

For the legal reasons given above, it is urged that the terms "in a form suitable for enteral but not parenteral administration" are fully supported by the original disclosure. The specification (e.g., page 5) expressly recites the options of "enteral" and "parenteral" forms of administration of both components. Since enteral and parenteral forms are optional, the option of "enteral but not parenteral" is adequately described.

As further proof of the correctness of the above position and proof of what one of ordinary skill in the art would understand as being described from applicants' disclosure, attached is a Declaration under 37 C.F.R. §1.132 by co-inventor Dr. Roger Kendall who is knowledgeable as to the meaning in the art of the terms pertaining to routes of administration of the components at issue. Particularly, the declaration sets forth that:

- one of ordinary skill in the art would interpret the term "enteral" as being distinguished from "parenteral,"
- it is known that enteral and parenteral administration forms have very different requirements, e.g., parenteral forms must be sterile,
- enteral forms need not be sterile,
- that the specification thus necessarily describes forms for enteral administration which are not suitable for parenteral administration (e.g., they are not sterilized) as one option, and

• the specification actually provides Examples where the administration form is suitable for enteral administration but not for parenteral administration.

Accordingly, the declaration verifies that one of ordinary skill in the art would consider the invention of the instant claims to be described in the original disclosure.

Similarly, the terms in the new claims reciting formulations which "are not sterilized" are fully supported by the original disclosure. The sterilizing step is disclosed as optional in the disclosure, thus formulations, which are not sterilized, are clearly described.

For the above reasons, it is urged that the 35 U.S.C. §112, first paragraph, rejection should be withdrawn and no similar rejection should be made against the current claims.

The Rejection under 35 U.S.C. §102

The rejection of claims 12-14 and 20 under 35 U.S.C. §102, as being anticipated by Belkowski, is respectfully traversed.

Belkowski discloses a method – albeit found to be undesired by Belkowski – involving separately administering a *Perna canaliculus* component orally (i.e., enterally) and DMG by injection (i.e., parenterally).

Belkowski fails to disclose either:

- (1) a "composition comprising a dimethylglycine component and at least one *Perna*canaliculus component, both in a form suitable for enteral but not parenteral administration",

 or
- (2) a "kit comprising a dimethylglycine formulation and a *Perna canaliculus* formulation, .. wherein both formulations are in a form suitable for enteral but not parenteral administration."

Compare instant claims 12 and 15. The dimethylglycine (DMG) used by Belkowski is parenterally administered so it obviously is not in a form, which is <u>not</u> suitable for parenteral

administration. On this basis, at least, the rejection under 35 U.S.C. §102 must be withdrawn since Belkowski does not disclosure an embodiment meeting each element of the instant claims.

As to claim 12 and claims dependent thereon, it is further urged that Belkowski fails to disclose a "composition comprising a dimethylglycine component and at least one *Perna canaliculus* component." In Belkowski, the components are separately administered and administered by separate routes, i.e., the *Perna canaliculus* is administered orally and the DMG by injection. There is no disclosure or suggestion that Belkowski ever provides a "composition" of the two components or that a composition is inherently formed. For this additional reason, it is urged that the rejection under 35 U.S.C. §102 must be withdrawn.

The Rejection under 35 U.S.C. §103

The rejection of claims 12-18, 20-21 and 38-41 under 35 U.S.C. §103 as being obvious over U.S. Patent No. 5,026,728 (Kendall et al.) in view of Caughey (1983 article) or Gibson (1980 article) or U.S. Patent No. 4,455,298 (McFarlane et al.) is respectfully traversed.

Applicants, in their prior Reply, pointed out that the data of record establish significant unexpected advantageous properties of the combination composition of matter of applicants' invention, which would not have been expected from the prior art. These unexpected, advantageous properties prove the nonobviousness of the claimed invention.

In the Office Action, the Examiner disregarded the data on the basis that the advantageous properties are "unclaimed limitations" and re-stated the position that it would have been obvious to combine two known anti-inflammatory compounds. As discussed below, the Examiner's position is legally incorrect and it was improper to disregard the data.

A showing of unexpected, advantageous properties for a composition of matter is

germane to the issue of nonobviousness whether the properties are recited in the claims or not. A compound (or composition) inherently possesses a set of properties unique thereto and a recitation of a compound or composition inherently subsumes the properties thereof. There is a multitude of examples from case law (see, e.g., In re Soni, 34 USPQ2d 1684, 1688 (Fed. Cir. 1995)) and patent practice wherein unexpected, advantageous properties flowing from a combination of compounds properly proved nonobviousness over prior art which suggested the compounds separately and *prima facie* suggested their combination. In most of these examples, the advantageous property was not recited in the claim, and such was not necessary since it was inherent in the combination. Such is the case here.

Further, that the references may suggest that both the PCE and DMG components are anti-inflammatories does not end the inquiry. While, for sake of argument, it could be said that such teachings create a prima facie case of obviousness, evidence of nonobviousness must be considered when making the ultimate determination of obviousness. It is certainly incorrect, as a matter of law, to ignore evidence of nonobviousness because it is believed a prima facie case of obviousness is established. See, e.g., In re Papesch, 137 USPQ 143 (CCPA 1963), and In re Oetiker, 24 USPQ2d 1443 (Fed. Cir. 1992). As stated in the Office Action, one of ordinary skill in the art may have expected that, since DMG and PCE were both known as anti-inflammatories, their combination would have been expected to provide the combined effect of their anti-inflammatory properties. However, if applicants can show that their combination provides other properties that would not have been expected by one of ordinary skill in the art, they are deserving of patent protection. Applicants have done so in the data (discussed below), which was, apparently, not considered in the Office Action. By such showing, the applicants have provided an advance in the art deserving of patent protection since there is no actual teaching of the combination, as claimed by applicants, and applicants have shown their combination to provide advantages that could not have been

expected by one of ordinary skill in the art.

The discussion in the prior Reply of the comparative data from the specification is reiterated below since it was not fully considered in the Office Action and should have been.

The specification provides side-by-side data comparing immune responses in a lupus mouse model for a DMG-PCE non-injected combination (enteral) according to the invention, for DMG orally alone and for PCE orally alone; see particularly Example 2 and Figures 2-5 of the instant specification. The data as a whole convincingly show that the combination of DMG/PCE provides an advantageous result, which is not merely the expected combined effect of DMG and PCE alone but an effect, which is **different in kind** than what would have been expected in the prior art.

Figure 2 shows that il-10 cytokine production is **increased** with DMG alone and only slightly decreased, if any (see error limits), with PCE ("PERNA") alone. But the il-10 production is surprisingly **significantly decreased** by the combination of DMG and PCE according to the invention. Figure 2 also shows that TNF-alpha levels are **decreased** with either of DMG or PCE alone but, surprisingly, **increased** by a combination of DMG and PCE. Thus, the data establish that the combined effect of DMG/PCE is not what would have been expected based on the effect shown by DMG or PCE alone.

The significance of this distinct result is discussed in Example 2; see page 11, first two full paragraphs. The effects shown for the combination of DMG/PCE in il-10 and TNF-alpha production are indicative of a shift from a Th2 type response to a Th1 response for these cytokines. Such a shift is of high significance to the immune response generated. See the previously submitted excerpt from Cellular and Molecular Immunology, 3rd. ed, Chapter 12: Cytokines, pp. 271-272, discussing that Th1 and Th2 are the two dominant subsets of cytokine profiles exhibited in immune responses. Accordingly, the demonstrated shift from a Th2 to Th1 type response for these cytokines effected by the DMG/PCE combination is an

unexpected result of high significance to the immune response exhibited.

The advantage of the DMG/PCE combination is further demonstrated in Figures 3, 4 and 5 which in each case show an advantage of the DMG/PCE combination over either of DMG or PCE alone in reducing CD8 and CD19 lymphocytic markers, reducing anti-dsDNA antibody levels, and reducing anti-ssDNA antibody levels. The CD19 results, anti-dsDNA antibody #1 and anti-ssDNA antibody results again show an effect from the combination different from that which would have been expected looking at the results for DMG and PCE separately.

Moreover, these test results represent a comparison against the "closest" prior art, i.e., use of DMG and PCE orally (enterally), alone. Under the alleged In re Kerkhoven rationale (see Office Action mailed September 26, 2000), the expectation in the art was that the result of the combined use of DMG and PCE should be the same as that for DMG alone and PCE alone in comparable amounts. This is what was compared in the Example 2 tests.

Belkowski's teachings are clearly further away from the claimed invention despite that DMG (injected) and PCE (orally) were both administered because Belkowski explicitly establishes that the combination does not work, i.e., it establishes an expectation in the art – from worse results – further away from the invention than that established under the Kerkhoven rationale – same results. Additionally, Belkowski differs in the mode of administration of DMG. Clearly then, the closest prior art under Kerkhoven are the teachings of using DMG alone, orally, and PCE alone, orally, which is the comparison applicants provided.

The data as a whole in the specification establish that the combination of DMG/PCE provides a significant and unexpected advantageous result over what would have been expected from the closest prior art teachings of use of either alone, e.g., orally or together as in Belkowski. The combination provides a result, which is different in kind from that expected by combining the effects of DMG and PCE administered alone. The data, thus,

clearly and convincingly proves nonobviousness even if the prior art provided a *prima facie* case for making the combination of DMG/PCE.

The Office Action also dismisses the evidence from the Belkowski disclosure, which actually teaches away from the claimed invention. It is alleged in the Office Action that the Belkowski teachings are not applicable because they relate to an artificial model. Applicants strongly disagree with the dismissal of this further evidence of nonobviousness. The model which Belkowski used is one that, at least he, considered useful in assessing the properties of PCE and DMG individually and in combination. There is no evidence of record supporting the allegation in the Office Action that this model provides no results of significance. To the contrary, the Belkowski teachings are highly significant as to what one of ordinary skill in the art would have expected from the combination of DMG and PCE because they are the only teachings in the prior art, which relate to any actual combination of DMG and PCE – albeit in a combination distinct from that of the instant claims. Contrary to backing up what may have been the prima facie view in the art – i.e., that combining the anti-inflammatories would provide a heightened effect over either alone – Belkowski teaches that the combination of PCE and DMG is less effective than PCE alone. This evidence must be considered and further bolsters the showing of nonobviousness by applicants.

For these reasons at least, the rejection under 35 U.S.C. §103 based on the combination of the Kendall '728 reference with Caughey or Gibson or McFarlane '298 should be withdrawn.

Additionally, it is urged that the method of use claims, particularly the method to treat lupus, are further distinguished from the prior art since the art fails to suggest combining DMG and PCE for treating lupus. While Kendall '728 provides a generic teaching which includes lupus in a list of autoimmune diseases treatable using DMG, the secondary references directed to the use of PCE provide no suggestion to use PCE for treating lupus.

Thus, while there, arguably, may be a prima facie case to combine DMG and PCE to treat

arthritis (overcome by the data above), there is no such *prima facie* case for treating lupus.

Accordingly, the claims directed to methods for treating lupus are even further distinguished

from the prior art. Similarly, the prior art fails to teach or suggest a method for effecting the

immune response recited in new claims 30-37. As discussed above, it has been shown that,

in fact, DMG and PCE alone effect immune responses differing from that of the combination

recited in these new claims.

It is submitted that the claims are in condition for allowance or, at least, remove some

issues for appeal. However, the Examiner is kindly invited to contact the undersigned to

discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this

response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

6hn A. Sopp, Reg. No. 33,103

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Filed: June 24, 2002

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FSC-6

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 12 and 15 have been amended to read as follows:

- 12. (Three Times Amended) A composition comprising a dimethylglycine component and at least one *Perna canaliculus* component, both in a non-injectable form suitable for enteral but not parenteral administration.
- 15. (Three Times Amended) A kit comprising a dimethylglycine formulation in a non-injectable form and a *Perna canaliculus* formulation in a non-injectable form, wherein the *Perna canaliculus* formulation comprises at least one *Perna canaliculus* component and wherein both formulations are in a form suitable for enteral but not parenteral administration.

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Jun. 18 2002 10:25AM

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

In the application of:

JUL 1 1 2002

Roger KENDALL et al.

Group Art Unit: 1644

TECH CENTER 1600/2900

Application No.: 09/316,001

Examiner: Ewoldt, G.

Filed: May 21, 1999

FOR METHODS AND COMPOSITIONS FOR MODULATING IMMUNE RESPONSE

AND FOR THE TREATMENT OF INFLAMMATORY DISEASE

DECLARATION UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents Washington, D.C. 20231

Sic

The undersigned, Roger V. Kendall, declares as follows:

- 1. My expertise to make the following statements is established in the attached "Biosketch".
- 2. I am the Vice President of Research and Development of the assignce, FoodScience Corporation of Essex Junction, Vermont, 05453.
- 3. The following statements are not made as an expert in the field of the invention claimed in the above-identification application. They are made in terms of what one of ordinary skill in the art would know and opine. I am able to make these statements as one of ordinary skill in the art because the concepts involved are of a very basic nature in the field of dietary supplements and pharmaceuticals.
- 4. I have been asked to comment on what one of ordinary skill in the art would necessarily understand from a reading of the specification of the above-identified

application, particularly in regard to the nature of the formulations which are disclosed as containing both N,N-dimethylglycine (DMG) and at least one *Perna canaliculus* (PCE) component.

- 5. The specification indicates to one of ordinary skill in the art that formulations containing both DMG and PCE are preferred. See, e.g., page 4, lines 5-6, page 5, lines 5-8 and 14-15, and page 8, lines 2-3, for example. These formulations can be prepared for pharmaceutical or dietary supplement purposes "using techniques that are well known in the art." (Page 5, lines 5-7). Dietary supplements are particularly preferred as can be seen from the text of original claims 14 and 16, for example.
- 6. These compositions or kits containing both DMG and PCE can be formulated to be administered by a variety of routes. See, for example, page 5, lines 20-23 which disclose that the formulations can be made "suitable for parenteral, enteral (e.g., oral) application." This passage unambiguously is referring to parenteral or enteral, as can be seen from the preceding paragraph which explicitly states that a preferred route for PCE administration is oral and that a preferred route for DMG is also oral. It then states that "DMG or PCE can also be administered by intramuscular injection, intra peritoneal injection, parenteral administration, etc." (Page 5, lines 15-19). Thus, parenteral or enteral administration is clearly disclosed, oral administration being preferred.
- 7. The terms "enteral" and "parenteral" are very basic ones well known in the field to those with ordinary skill in the art. For example, "enteral" is defined as: "Within, or by way of, the intestine or gastrointestinal tract, especially as distinguished from parenteral." The term "parenteral" is defined as: "By some other means than through the gastrointestinal tract; referring particularly to the introduction of substances into an organism by intravenous, subcutaneous,

intramuscular, or intramedullary injection." (Stedman's Medical Dictionary, 26th Edition, Ed. Spraycar, Williams, & Wilkins (1995))

- 8. Formulations for these two administration routes have very different requirements, which are well known to those of ordinary skill in the art. Indeed, the basic requirements are well known generally even to the lay public. For instance, it is very well known that formulations for parenteral administration, which involve injection into the human or animal body as can be seen from the basic definition, must be sterile. It is even more well known that matter which is administered orally to humans or animals need not be and usually is not sterile, e.g., food. One of ordinary skill in the art would immediately know that formulations disclosed in the above-identified application which are suitable for parenteral administration must be sterile and that those suitable for enteral, e.g., oral, administration need not be sterile.
- 9. Regarding this matter of sterility, a skilled worker reading the specification need not even rely on this fundamental knowledge. Rather, the specification itself informs one of ordinary skill in the art that the preparations of the invention "can be sterilized," e.g., page 5, lines 28-29. Thus, even if it had been possible that one of ordinary skill in the art would not contemplate the issue of sterility in connection with the parenteral (where sterility is necessary) and enteral (where sterility is not necessary) formulations of the application, the mentioned passage would make these facts explicitly part of the disclosure.
- 10. Based on the foregoing facts, one of ordinary skill in the art would necessarily and inevitably know, upon reading the above-application, that (1) the disclosed formulations can be either parenteral or enteral and (2) depending on whether they were or were not sterilized ("can be sterilized;" see paragraph 9 above), the formulations could be suitable for both parenteral or enteral application (when they are sterilized) or suitable for enteral application but not parenteral application

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(when they are not sterilized). These concepts would necessarily be appreciated by one of ordinary skill in the art because the expression "can be sterilized" admits of only two possibilities, i.e., sterilized formulations or not-sterilized formulations.

- For the foregoing reasons, one of ordinary skill in the art, upon reading the above-11. identified application, that would find a description of formulations which are suitable for enteral but not parenteral application, e.g., the clearly disclosed nonsterilized ones. This would be especially clear in view of the examples of the application since the DMG utilized therein (AANGAMIK® FoodScience Corporation, Essex Junction, Vermont) (page 10, lines 9-11) and the PCE used therein (Perna, FoodScience Corporation, Essex Junction, Vermont) (page 10, lines 14-15) are known in the field as commercial products that are not sterilized.
- I hereby declare that all statements made herein of my own knowledge are true 11. and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

6/18/02

Kerdall

FAX NO.: 8028780549



JUL 1 1 2002

TECH CENTER 1600/2900

BIOSKETCH

Vice President of Research and Development, FoodScience Corporation, 20 New England Drive, Essex Junction, VT 05452

Academic Background

FOODSCIENCE

1965 - B.S. Chemistry, University of Vermont, Burlington, Vermont

1970 - Ph D. Organic Chemistry, Penn State University, University Park, Pennsylvania

Vice President of Research and Development, FoodScience Corporation, Essex Jct., VT Professional Experience 1999 - Present

- Responsible for quality control on all products
- Provide technical support for marketing of products
- Developed new and improved product formulations
- Direct research activities of the corporation

Associate Professor of Chemistry, University of Bridgeport, Bridgeport, CT 1997 - 1999

- Supervised and remodeled chemistry program to meet expanded role of department
- Received university research grant in amino acid chemistry
- Investigated the anti-inflammatory properties of Perna canaliculus

Associate Professor of Chemistry, Ambassador University, Big Sandy, TX 1990 - 1997

- Chairman of the Chemistry Department
- Taught courses in General, Organic and Biochemistry
- Supervised Undergraduate Research

Director of Research and Development, FoodScience Corporation, Essex Jct., VT 1977 - 1990

- Directed total quality control of corporate products
- Developed and reformulated over 60 successful products
- Coordinated research activities with other institutions

Assistant Professor of Chemistry, Ambassador College, Pasadena, CA 1974 - 1977

Taught classes and directed undergraduate research

Research Chemist and Project Leader, American Cyanamid Co, Princeton, NJ 1970 - 1974

- Synthesized over 300 compounds of drug screening
- Received two patents on product research
- Assisted in product process development and pilot plant operations

Pertinent Publications and Patents

- 1. Kendall, R. Lawson JW., May 2000, Recent Findings on N,N-Dimethylglycine (DMG), A Nutrient for the New Millennium, Townsend Letter for Doctors and Patients, pp 75 - 85
- 2. Kendall, R, Lawson JW and LA Hurley. July 2000. New Research and a Clinical Report on the Use of Perma Canaliculus in the Management of Arthritis. Townsend Letter for Doctors and Patients, pp 99-111.
- 3. Kendall, Roger V., 1998, Therapeutic Nutrition in Veterinary Practice In Schoen, A. and Wynn, S., editors: Complementary and Alternative Veterinary Medicine, St. Louis, Mosby.
- 4. Kendall, Roger V., 1998, Basic and Preventive Nutrition for the Cat, Dog and Horse in Schoen, A and Wynn, S., editors: Complementary and Alternative Veterinary Medicine, St. Louis, Mosby.

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6. Kendall, R.V. and J.W. Lawson, June 1991, Treatment of Arthritis and Inflammation Using N,N-Dimethylglycine U.S. Patent # 5,026,728.

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- 15. Kendall, R.V. and R.A. Olofson, 1970, 1,3,4-Selenadiazole J. Org. Chem. 35:806
- 16. Kendall, R.V., 1970, Structural Effects on the Kinetic Acidity of Ring C-H in Heteroaromatic Systems Ph.D. Thesis, Pennsylvania State University.
- 17. Duthie, A.H. and R.V. Kendall, 1965, New Milk Phospholipids Extraction Method J. Dairy Science. 48:1368.